



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/556,224 | 09/27/2006 | Martin Hendrix | 01-2116 | 3652 |
| 28519 7590 01/22/2010 MICHAEL P. MORRIS BOEHRINGER INGELHEIM USA CORPORATION 900 RIDGEBURY RD P O BOX 368 RIDGEFIELD, CT 06877-0368 | | | | |
| EXAMINER MOORE, SUSANNA | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1624 | | | | |
| NOTIFICATION DATE | | DELIVERY MODE | | |
| 01/22/2010 | | ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO.e-Office.rdg@boehringer-ingelheim.com

Office Action Summary

Application No.

10/556,224

Applicant(s)

HENDRIX ET AL

Examiner

SUSANNA MOORE

Art Unit

1624

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 13-16 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 2 is/are allowed.
- 6) ☒ Claim(s) 3-6, 9 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB06)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notes of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date 11/5/2009

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/5/2009 has been entered.

Response to Amendment

Applicant's arguments, see Remarks, filed 11/5/2009, with respect to Office Action mailed 6/11/2009 have been fully considered. In summary, claims 1-7, 9 and 13-17 are currently pending. Claims 1-6, 9 and 17 are currently under consideration. Claims 7 and 13-16 are currently withdrawn due to nonelected subject matter and election by original presentation. Claims 15-17 are new claims. Based on the restriction requirement claim 17 is under consideration since it is a composition claim.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 11/5/2009 was filed after the mailing date of the Non-final Office Action on 10/20/2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

The objection of the disclosure is **withdrawn** based on the remarks.

Claim Rejections - 35 USC § 112

The rejection of claims 1-6 and 9 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutically acceptable salts of a compound of formula (I) does not reasonably provide enablement for a solvate of compound of formula (I) of claim 1 is **withdrawn** based on the amendments.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-6, 9 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-6 recites the limitation "pyridyl N-oxide" in the definition of R². There is insufficient antecedent basis for this limitation in the claim.

Claim 17 is indefinite due to the language used in the claim. The preamble states "A pharmaceutical composition comprising a compound according to claim 1..." but claim 17 does not include a carrier, diluent or excipient. If Applicant intends a composition, as the preamble currently reads, please include a carrier, diluent or excipient. If claim 17 is intended as a compound claim, please change the preamble to state so. Therefore, the claim is indefinite since it is uncertain what Applicant is attempting to claim.

Claim Rejections - 35 USC § 103

The rejection of claims 1-4 and 9 under 35 U.S.C. 103(a) as being unpatentable over Cheng et. al. (J. Org. Chem, 1958, (23) 191-200) is **withdrawn** based on the amendments.

Allowable Subject Matter

Claim 1 and 2 are allowable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/
Examiner, Art Unit 1624